

# **OFFICE OF EXTRAMURAL RESEARCH REVISED GUIDANCE REGARDING IACUC APPROVAL OF CHANGES IN PERSONNEL INVOLVED IN ANIMAL ACTIVITIES**

**RELEASE DATE:** June 6, 2003

**NOTICE:** NOT-OD-03-046

National Institutes of Health (NIH)

This notice amends guidance provided in 1995 to Public Health Service (PHS) awardee institutions and Institutional Animal Care and Use Committees (IACUCs) concerning IACUC approval of changes in personnel involved in animal activities. This is in accord with efforts to reduce the regulatory burden of provisions of the PHS Policy on Humane Care and Use of Laboratory Animals (PHS Policy) and, as applicable, the USDA animal welfare regulations (AWRs). The Office of Laboratory Animal Welfare (OLAW), NIH, and the USDA Animal Plant Health Inspection Service (APHIS) concur with the guidance provided in this notice.

## **BACKGROUND**

PHS Policy (IV.B.7) (<http://grants.nih.gov/grants/olaw/references/phspol.htm>) and USDA regulations (9CFR 1, chapter 1, Part 2, 2.31(c)(7)) (<http://www.nal.usda.gov/awic/legislat/awafin.htm>) require the IACUC to "review and approve, require modifications in (to secure approval) or withhold approval of proposed significant changes regarding the use of animals in ongoing activities." In 1995, the NIH Office for Protection from Research Risks, now OLAW, published guidance regarding examples of "significant change" to approved research protocols (Lab Animal 24 (9):24-26, 1995)(<http://grants.nih.gov/grants/olaw/references/laba95.htm>). This guidance was intended to assist IACUCs in determining when a full or designated member review process is required under the provisions of the PHS Policy and the USDA AWRs. One of the examples of "significant change" provided was "...changes in personnel involved in animal procedures;..."

The rationale for that guidance was based on the need for the IACUC to ensure the performance-based outcome that all personnel conducting procedures on animals are appropriately identified, adequately trained and qualified, and that they are enrolled in applicable occupational health and safety programs.

## **IACUC APPROVAL OF CHANGES IN PERSONNEL INVOLVED IN ANIMAL ACTIVITIES**

Members of the research community have pointed out circumstances under which strict adherence to this earlier guidance may be unnecessarily burdensome on IACUCs and research teams, without adding to the intended protections. For example, IACUC approval of the replacement for a key research technician or post doctoral fellow on a protocol may entail prolonged delays in a research project, even when the individual named as a replacement has already been fully certified by the IACUC as qualified to perform the same procedures on a different protocol. In addition, some institutions have applied full or designated review requirements for adding individuals with minimal direct involvement in animal procedures to the protocol.

OLAW, in consultation with USDA, APHIS, Animal Care, is hereby revising the 1995 guidance on review mechanisms for personnel changes on a protocol. IACUCs may, by institutional policy, classify certain proposed additions and changes in personnel, other than the Principal Investigator, as "minor" provided that an appropriate administrative review mechanism is in place to ensure that all such personnel are appropriately identified, adequately trained and qualified, enrolled in applicable occupational health and safety programs, and meet other criteria as required by the IACUC. The IACUC remains responsible for confirming that all IACUC review criteria regarding personnel training and qualifications are maintained and documented (PHS Policy IV,C,1 and 9CFR 1, chapter 1, Part 2, 2.31). Institutions will be held accountable for ensuring the performance-based outcome that all individuals involved in animal-related activities are competent to do so.

This guidance is intended to provide substantial reduction of burden on IACUCs and research teams without diminishing the crucial oversight of personnel training and qualifications.

## **INQUIRIES**

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